

**RESMED**Swift LT  
Traditional 510k**510(k) SUMMARY***[As required by 21 CFR 807.92(c)]***Date Prepared** December 18<sup>th</sup>, 2007**Official Contact** Mr. David Thomson,  
Senior Regulatory Affairs Manager**Device Trade Name** Swift™ LT**Device Common Name/  
Classification Name** Vented Nasal Mask;  
Accessory to Noncontinuous Ventilator (IPPB)**Classification** 21 CFR 868.5905, 73 BZD (Class II)**Predicate Devices** Mirage Swift (K042403)  
Ultra Mirage II Mask (K050359)**Description** The Swift LT provides an interface such that airflow from a positive pressure source is directed to the patient's nose. The mask is held in place with adjustable headgear that straps the mask to the face.

Swift LT is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product.

Swift LT is a prescription device supplied nonsterile.

**Intended Use** The Swift LT channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Swift LT is:

- to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed.
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

**Technological  
Characteristics  
comparison** Comparison with predicate Mirage Swift  
The new device and the predicate mask, provide a seal via silicone interface. Both masks are offered in various sizes to ensure adequate fit over the extended patient population.Both the masks incorporate vent holes to provide continuous air leak to flush out and minimize the amount of CO<sub>2</sub> rebreathed by the patient. The design of the mask components is such that the incorporation of these vent-holes does not interfere with the intended performance of the masks.

Both the masks connect to a conventional air delivery hose between the mask and the positive airway-pressure source via standard conical connectors (ref: ISO 5356-1:2004)

Both the masks are constructed using molded plastic and silicone components and fabric / nylon headgear. All the

components of both the masks are fabricated using materials deemed safe. (ref: ISO 10993-1).

Both the new device and the predicate are designed to operate on the same *Mirage* or *Swift* ResMed flow generator settings. The pressure-flow characteristics and flow impedance of both the new device and the predicate device are substantially equivalent.

Both the new device and the predicate device can be reused in the home and hospital / institution environment.

The main differences between Swift LT and Mirage Swift is in the number of components, their design/geometry and how individual components interface with each other. Both the masks are designed and constructed under ResMed's 21 CFR Part 820 compliant Quality Management System.

**Clinical Data** Use of vented nasal masks with CPAP or Bilevel therapy is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the Swift LT, as was the case with the predicate device.

**Performance Data** Comparison with predicate Ultra Mirage II  
The CO2 performance of the new device and the predicate device are substantially equivalent.

**Substantial Equivalence Conclusion** Swift LT is substantially equivalent to the predicate devices:

- it has the same though reworded intended use;
- it has similar technological characteristics to both predicates;
- it does not raise new questions of safety and effectiveness;
- it is at least as safe and effective as the predicate devices Mirage Swift and Ultra Mirage II



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 20 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

ResMed Limited  
C/O Mr. David D' Cruz  
Vice President, Clinical & Regulatory Affairs  
ResMed Corporation  
14040 Danielson Street  
Poway, California 92064-6857

Re: K073638  
Trade/Device Name: Swift™ LT  
Regulation Number: 21 CFR 868.5905  
Regulation Name: Noncontinuous Ventilator (IPPB)  
Regulatory Class: II  
Product Code: BZD  
Dated: March 6, 2008  
Received: March 10, 2008

Dear Mr. D' Cruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

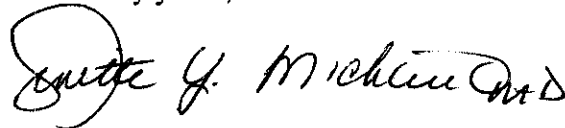
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Indication for Use**

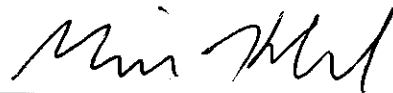
510(k) Number (if known):

Device Name: **Swift™ LT****Indication for Use**

The Swift LT channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Swift LT is:

- to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed.
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices510(k) Number: K073638Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

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